REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated May 22, 2002 are respectfully requested. The applicant petitions the Commissioner for a 2-month extension of time. A separate petition accompanies this amendment.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned **"Version with markings to show changes made."**

I. Amendments

Claim 1 is amended to recite that the axial connectors "join one or more confronting peaks" of adjacent tubular members. Basis for this amendment is found on page 6, lines 3-9.

II. Rejections under 35 U.S.C. §102

Claims 1 and 5 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Johnson (U.S. Patent No. 6,253,443).

Claim 1 was rejected under 35 U.S.C. §102(e) as allegedly anticipated by Cox (U.S. Patent No. 6,171,334).

Claims 1 and 5 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Brown *et al.* (U.S. Patent No. 6,348,065).

These rejections are traversed for the following reason.

A. The Invention of Claim 1

The invention relates to a stent designed for catheter delivery to a target neurovascular site. The stent is comprised of the following elements:

(1) a plurality of expandable tubular members, (i) each member being composed of a continuous wire element forming a plurality of wave segments, (ii) each segment containing a pair of opposite looped peaks and (iii) having a wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave on

B

proceeding from a peak toward opposite peaks, increases monotonically with an inflection point therebetween, and (iv) in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks, and

(2) axial connectors joining one or more confronting peaks of adjacent tubular members,

(3) wherein radial expansion of the stent from its contracted to its expanded state is accommodated by movement of adjacent wave-segment peaks away from one another, without significant change in the axial dimension of the stent.

B. The Prior Art

JOHNSON describes a stent that serves as a drug delivery vehicle. The stent is formed of a porous material in which the drug is embedded (Col. 1, lines 34- 41). Exemplary stent structures shown in Fig. 2 and Fig. 5 consist of series of wire members (22) and interconnections (24). The interconnections join adjacent members by connecting offset adjacent peaks.

COX describes a stent comprised of nested, serpentine elements (Col. 2, lines 13-15; Figs. 1-7).

BROWN *ET AL.* describe a stent consisting of adjacent segments in an undulating pattern, where the adjacent segments are substantially parallel struts (Col. 2 line 65 to Col. 3, line 1).

C. Analysis

According to the MPEP § 2131: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

The stent illustrated in Figs. 1a, 1b, 3, 4a, 4b of Johnson do not include a "plurality of wave segments" with "opposite looped peaks" (elements 1(i) and 1(ii)). The

B

stents shown in Fig. 2 and Fig. 5 of Johnson fail to show axial connectors joining one or more confronting peaks of adjacent tubular members. The stent in Figs. 2 and 5 of Johnson show the connectors situated to join offset adjacent peaks.

With respect to the Cox reference, the stent embodiments illustrated in Figs. 1, 2, and 3 nowhere show element 1(iv) of the present invention. Namely, the stents fail to provide the presently claimed element that "in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks." The stent disclosed in Figs. 1, 2, and 3 are in a contracted state, and, as can be seen by viewing the drawings, there is not a minimum point in adjacent sides of a wave achieved at a location intermediate opposite peaks.

With respect to the stent in Figs. 4 and 7 of Cox, the stents illustrated in these figures to provide presently claimed element (2): "axial connectors joining one or more confronting peaks of adjacent tubular members." As seen in Figs. 4 and 7 of Cox, the interconnections are not between adjacent tubular members, but are between nested loops.

The stent described in Brown *et al.* consists of adjacent segments in an undulating pattern, where the adjacent segments are substantially parallel struts (Col. 2 line 65 to Col. 3, line 1). Parallel adjacent segments by definition cannot and do not provide the claimed elements 1(iii) and 1(iv), namely that in the stent's expanded state, the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point therebetween, and (iv) in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks.

Since none of the cited references individually show each and every claimed element, the invention is not anticipated. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §102.

III. Rejections under 35 U.S.C. §103

Claims 2-4 were rejected under 35 U.S.C. §103 as allegedly obvious over Brown *et al.* or Johnson or Cox in view of Schnepp-Pesch *et al.*, U.S. Patent No. 5,860,999.

B

Claims 6-12 were rejected under 35 U.S.C. §103 as allegedly obvious over Brown *et al.* or Johnson or Cox in view of Schnepp-Pesch *et al.*, U.S. Patent No. 5,860,999 and in view of Parodi, U.S. Patent No. 5,954,764.

These rejections are respectfully traversed for the following reasons.

A. The Prior Art

JOHNSON is described above.

COX is described above.

BROWN *ET AL.* is described above.

SCHNEPP-PESCH ET AL. is summarized in Applicants' amendment filed March 8, 2002.

PARODI is summarized in Applicants' amendment filed March 8, 2002.

C1. Analysis: Rejection of Claims 2-4

One of the three basic criteria to establish a prima facie case of obviousness is that the prior art references (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. § 2143.

As noted above, the cited primary references of Brown *et al.*, Johnson, and Cox individually fail to show or suggest each of the claim limitations.

Brown *et al.* is limited to a showing of stents having parallel adjacent segments, which are unable to result in a stent having an expanded state where the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point therebetween. Nor can parallel segments provide a stent having a contracted state where the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks.

B

Johnson fails to show axial connectors joining one or more confronting peaks of adjacent tubular members. The stent in Figs. 2 and 5 of Johnson show the connectors situated to join offset adjacent peaks.

The stents in Cox lack either a connector joining one or more confronting peaks of adjacent tubular members or stent segments that achieve an expanded state where the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point therebetween.

The stent of Schnepp-Pesch is relied upon solely to provide the shape memory alloy of dependent claims 2-4. The teaching does not make up for deficiencies in showing the claimed structural features or the advantages inherent in the structural features, for all the reasons given in Applicants' amendment filed March 8, 2002.

Thus, claims 2-4 are not rendered obvious by the combination of Brown *et al.* or Johnson or Cox in view of Schnepp-Pesch *et al.*

C2. Analysis: Rejection of Claims 6-12

All of the arguments in C1 above are relevant to the rejection of claims 6-12. Namely, the cited combination of references fails to show or suggest every claim element. The Parodi reference is cited to provide a teaching of the cathether and pusher set forth in pending claims 6-12 and does not provide the elements missing from the combined teachings of Brown *et al.* or Johnson or Cox in view of Schnepp-Pesch *et al.*.

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

IV. Conclusion

In view of the foregoing, the applicant submits that the claims pending in the application patentably define over the cited art. A Notice of Allowance is therefore respectfully requested.

B

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4402.

Respectfully submitted,

Date: 10/18/02

Judy M. Mohr
Registration No. 38,563

Correspondence Address:
Customer No. 22918
(650) 838-4300

B

VERSION WITH MARKINGS TO SHOW CHANGES MADE

On page 3:

In a preferred embodiment, the wire elements are formed of a NiTi shape memory alloy, and radial expansion is achieved by releasing the stent from such catheter. The stent of this embodiment may have a stress-induced martensite phase at body temperature, and/or an austen[t]ite phase transition temperature below body temperature.

On page 8:

At the same time, the element can undergo a severalfold radial expansion by virtue of the ability to be close packed in a contracted state (unlike a sin wave), and still provide significant expansion between wave segment[s] arms. This is in contrast to a sin-wave wire element in which compression at the peaks, and thus the number of wave segments that can be accommodated in the contracted state, is limited.

On page 9:

In one general embodiment, the stent is formed of a shape-memory alloy having a final austen[t]ite transition temperature of between about 25°C and 37°C. This feature allows the stent to be carried in the catheter in a martensitic state, and assume its preformed, austen[t]itic shape when expelled from the catheter and exposed to the higher body temperature at the target site. In another embodiment, the shape-memory alloy has a transition temperature M_d greater than 37°C, below which the alloy retains sufficient stress-induced martensitic property to allow placement of the stent at or above its A_f. In other words, this allows the stent to be carried in the catheter in a stress-induced martensitic (SIM) state, and recover its preformed, austen[t]itic shape when released from the constraints of the catheter, at a temperature that may be substantially above the final austen[t]ite temperature without significant plastic, or otherwise

permanent deformation. In this embodiment, the final austen[t]ite temperature may be quite low, *e.g.*, 4°C, or it may be room temperature or higher.

On page 10:

Nitinol cylindrical tubes having a martensite temperature M_D below which the alloy can assume a stress-induced martensitic condition while being stressed to the extent necessary to place or otherwise use the device, of greater than about 37°C, preferably greater than about 40°C, are also prepared according to known methods, *e.g.*, U.S. Pat. No. 4,505,767. For example an ideal alloy would act, at about 37°C, as a constant force spring over a strain range up to about 5% or more. This is a measurement of the degree to which an alloy, at a given temperature, can be strained in a purely austen[t]itic state by the formation of stress-induced martensite without significant plastic deformation. In other words, the strain caused by the application of a given stress at a given temperature is substantially recoverable. In practice, the maximum stress realized occurs sometime during the process of placing a nitinol device at a given temperature. Accordingly, a suitable alloy will provide a device that is capable of substantially recovering its austen[t]itic shape without significant plastic deformation, upon placement in the body.

1. (Twice Amended) A stent designed for catheter delivery to a target neurovascular site via a tortuous path in a contracted state, and deployment at the target site in an expanded state, comprising

a plurality of expandable tubular members, each member being composed of a continuous wire element forming a plurality of wave segments, each segment containing a pair of opposite looped peaks and having a wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point therebetween, and in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks, and

B

axial connectors joining one or more confronting peaks of adjacent tubular members,

wherein radial expansion of the stent from its contracted to its expanded state is accommodated by movement of adjacent wave-segment peaks away from one another, without significant change in the axial dimension of the stent.

4. (Amended) The stent of claim 2, which has an [austentite] austenite phase transition temperature below body temperature.

B